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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BOSTON, MA 02210-2604			1762	
			DATE MAILED: 06/23/2006	5

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)			
	09/849,065	HALVERSON, WARD DEAN			
Office Action Summary	Examiner	Art Unit			
	Marianne L. Padgett	1762			
The MAILING DATE of this communication apperiod for Reply	ppears on the cover sheet wit	th the correspondence address			
A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING I - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory perior. Failure to reply within the set or extended period for reply will, by statu. Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a red d will apply and will expire SIX (6) MONT ate, cause the application to become ABA	CATION. Sply be timely filed ITHS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed on 3/9.	<u>/2006 & 4/24/2006</u> .				
2a) This action is FINAL . 2b) ☐ Th	This action is FINAL . 2b)⊠ This action is non-final.				
3) Since this application is in condition for allow	•	•			
closed in accordance with the practice under	Ex parte Quayle, 1935 C.D.	. 11, 453 O.G. 213.			
Disposition of Claims					
4) Claim(s) <u>1,4-8,10-19,21-28,31,33-39,50 and</u> 4a) Of the above claim(s) is/are withdr	<u> </u>	application.			
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1,4-8,10-19,21-28,31,33-39,50 and</u>	52-58 is/are rejected.				
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction and	or election requirement.				
Application Papers					
9)☐ The specification is objected to by the Examir	ner.				
10) The drawing(s) filed on is/are: a) □ ac	ccepted or b) objected to b	by the Examiner.			
Applicant may not request that any objection to th	e drawing(s) be held in abeyan	ce. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the corre	• • • = •				
11)☐ The oath or declaration is objected to by the E	Examiner. Note the attached	Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreig a) All b) Some * c) None of:	n priority under 35 U.S.C. §	119(a)-(d) or (f).			
 Certified copies of the priority document 	nts have been received.				
Certified copies of the priority documer	nts have been received in Ap	oplication No			
Copies of the certified copies of the pri	•	received in this National Stage			
application from the International Bure	. , , ,				
* See the attached detailed Office action for a lis	st of the certified copies not r	received.			
Attachment(s)					
1) Notice of References Cited (PTO-892)		ummary (PTO-413)			
 Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)/Mail Date formal Patent Application (PTO-152)			
Paper No(s)/Mail Date	6) Other:				

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/24/2006 has been entered.

It is noted that applicants' RCE request/transmittal indicates that both the previously submitted (after final amendment of 3/9/2006) & the enclosed amendment submitted with the transmittal (4/24/2006) are to be entered, however the examiner notes that the 4/24/2006 amendment is identical to the 3/9/2006 amendment, hence is technically informal/noncompliant, as it is making changes that are already present in the preceding amendment. However, as both amendments do appear to be identical, the examiner will merely treat the latter as a copy of the former, and examine the response accordingly.

2. Claims 21 & 31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Independent claim 1 as amended now requires "coatings said treated surface with a selected bioactive material", however claim 21, as pointed out in the advisory action, provides for the options of "said coating material is selected from the group consisting of an organic polymer, an inorganic material, and a bioactive material", which improperly broadens the scope from the limitation of the independent claim to include coatings that need not be bioactive materials. Note, as Markush group species are supposed to be mutually exclusive, the implications of the Markush group of claim 21 are that neither the organic polymer, nor the inorganic material are intended to be bioactive, unless the species are improperly not mutually exclusive.

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Claim 31 provides options of effects of the plasma, only one of which appears to overlap with the amended options of independent claim 1, the option of "bonds scission of the surface" (different phrasing same meaning as "chemical bond scission"), such that it appears that applicants may be broadening the scope from the options required by the independent claim.

Alternately, claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as it is unclear whether the options of claim 31 are in addition to the effects required in claim 1 as amended, or whether they are a different set of alternatives, overlapping with, but also expanding the scope required in the independent claim.

- 3. Claim 52 is objected to because of the following informalities: in claim 52, line 2, the limitation "a bioactive material" uses the article "a", such that it does not show antecedent basis to the amended limitation in independent claim 33 directed to "coating...with a selected bioactive material", but neither does it clearly differentiate from that limitation, so the dependent claim may or may not refer to the same limitation. While the office no longer officially considers this an informality problem, applicants may consider clarifying their claim language. Appropriate correction is required.
- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1, 4-8, 10-19, 21-28, 31, 33-39 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramanian (5,914,115) in view of Williams et al. (4,927,676), further considering Conover et al. (6,136,389) or Yamazaki (5,601,883) and/or Kieser et al (5,053,244) and/or

Wilhelm (4,897,285), all references previously discussed in sections 5-9 of the 12/17/04 action & 4-8 of paper # 9, mailed 3/24/04.

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The emphasis of the claims has changed over the course of the prosecution due to the various amendments, such that it is appropriate to change or rearrange the combination of references.

Subramanian (5,914,115) teach functionalizing the surface of a medical device, inclusive of various catheters or vascular stents, etc., where elongated tubular members with lumen extending through the length are particularly noted, and where the plasma treated surface is further contacted with a bioactive agent, such as antithrombogenic coating like heparin, or antimicrobial or antifungal agents, or growth factors, etc. A preferred embodiment for functionalization uses RF glow discharge plasma (methane/oxygen plasma or water/oxygen plasma or acrylic acid/carrier gas like He or Ar, etc.) to form chemically reactive groups on the surface, with plasma species interacting with the surface in a variety of reactions including breaking of bonds and/or forming of new bonds to attach functional groups, such as hydroxyl groups or carboxyl groups or amine groups etc., where modifications are noted to effect the contact angle, thus include reactions that are inherently increasing surface energy via the plasma treatment. While Subramanian (115) does not explicitly discuss treating the interiors of the tubes or tubular members, they do teach "the invention also provides general methods for treating a surface of a medical device to inhibit thrombosis which involves causing a bioactive agent to become covalently bound to a medical device surface exposed to blood flow...". Since the surface of catheters & vascular stents, etc. which are exposed to blood flow are expected to be the interior or the lumen of the tubes, this teaching is considered to be suggesting that interior coating is occurring. Again, specifically note abstract; col. 1, lines 21-33 & 51-63; col. 2, lines 35-col. 3, lines 32 & 54-col. 4, lines 36 & 48-52+, and examples starting col. 4, line 65-col. 5, line 30+ for the plasma pretreatment embodiment. Subramanian (5,914,115) differs from the claims by employing a generic low-temperature or glow discharge RF

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plasma, instead of an electron cyclotron resonance (ECR) plasma, which is spatially localized, and hence parameters associated therewith.

Williams et al. (676) teach a process which is specifically directed to plasma treatment of the lumen walls of a small diameter plastic tubing in order to adhere endothelial cells to providing antithrombogenic surface to vascular grafts. Williams et al. further teach that a conventional plasma generator may be used where such generators include radiofrequency or microwave frequency equivalently, noting that useful high-frequency power sources range through radio frequency into microwave frequencies, with useful techniques inclusive of microwave guide techniques (abstract; summary; cols. 3-6, especially col. 4, lines 23 for tubing, 25-40 for plasma types, 48-59 for gases as claimed & as used in Subramanian, and col. 5, lines 30-36 for addition of functional groups also consistent with the primary reference). It would have been obvious to one of ordinary skill in the art given the analogous teachings of Williams et al. and Subramanian, that conventional high-frequency plasmas that employed microwave frequencies would have been expected to be equivalently useful in the processes of Subramanian, as Williams et al. showed the equivalent usefulness of RF glow discharge & microwave plasmas for like plasma pretreatment of tubular substrates, although narrower purposes/enduse directed to a more specific bioactive agent deposited thereafter. As Williams et al. (676) does not provide a specific example of microwave generators or microwave waveguide techniques, only the general suggestion of their usefulness, it would have been obvious to one of ordinary skill in the art to look to the prior art for suitable microwave plasmid techniques that would be capable of treating tubular substrates as taught, a specially given the teaching's implied suggestion that they are known to be capable of treating the interior of tubular substrates, i.e. the lumen.

The tertiary references of Conover et al. or Yamazaki (883) and/or Kieser et al (5,053,244) and/or Wilhelm (4,897,285), as has been previously discussed, all provide teachings on known microwave ECR plasmas that are capable of plasma treating various shaped substrates, including tubular & their interiors,

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hence would have been obvious to supply a means for treating these type of substrates with microwave plasmas as suggested by the combination of Williams and Subramanian. Specifically, Conover et al. is discussed below, where the provided ECR details & reasons for obviousness of specific parameter ranges, would have been expected to be applicable, with routine experimentation for specific materials and apparatus to the above combination.

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Alternately, Wilhelm (285) teach at ECR plasma technique specific to treating the internal surfaces of pipes or lengthy hollow microwave guides, but further teach that their "invention is generally suitable for providing all coatings which can be produced by conventional thermal or plasma enhanced CVD methods..." (summary, especially col. 2, lines 11-13, thus suggesting its applicability to treating the interiors of any hollow objects that require plasma treatment. Further note that Wilhelm (285) teach that the pressure in the waveguide/hollow object, the magnetic field strength and the localized area thereof & the microwave frequency & power are all selected so that ECR occurs in the desired area to trigger the discharge reaction in the gas supplied for furnishing the treatment/coating (col. 2, lines 57-68), suggesting relationships of applicant's claimed conventional formula & parameter ranges determined the routine experimentation as previously argued.

Alternately, Kieser et al. teacher multiplicity of arrangements of microwave input, gas input & magnetic field in order to localize ECR to permit a locally controlled ignition of plasma, with substrates supplied either on a substrate support (3) which is moved past the localized plasma or via spooled material (abstract; figures; col. 2, lines 42-58; col. 3, lines 45-62; col. 4, lines 14-col. 5, lines 20+). Teachings of Kieser et al. include treatment of three-dimensional substrates on the support and note that arrangements of the microwave window and magnetic fields may be varied in many ways, but what is important is only the relationship between the substrate surface to be treated in the region of electron cyclotron resonance, teachings (col. 5, line 58-68; col. 8, lines 7-16), which would have been expected to

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be applied by one of ordinary skill in the art to the combination of Williams & Subramanian to supply the suggested conventional microwave plasma.

Alternately, Yamazaki (883) teaches ECR microwave enhanced plasma treatment of various shaped substrates inclusive of cylindrical ones whose entire external surface is treated, but as these objects are present in their entirety in the ECR plasma gas and region, cannot be considered to exclude treatment also of the interior, at least in part, as discussed in previous actions (abstract; figures; column 2, lines 9-32 & 54-62; column 3, lines 40-column 4, line 40 column 5, lines 24-48+; with column 6, lines 61-68 suggesting further equivalent usages between ECR microwave plasma and glow discharge are plasmas). Therefore, depending on the overall shape of the particular hollow tubular medical device desired to be plasma treated, it would have been obvious to one of ordinary skill in the art to employ the ECR microwave plasma teachings of Yamazaki (883) to supply details for the combination of Williams & Subramanian's suggested conventional microwave plasma, especially considering hollow tubular substrates, such as the stent illustrated in Subramanian's figure 5, whose interior would have been expected by one of ordinary skill to be effectively treated by a configuration suggested by Yamazaki, as it would allow movement of plasma gasses to all parts of such a woven stent. Note that applicant's claimed treatment of inner surfaces does not exclude treatment of exterior surfaces simultaneously in these claims.

While any of these tertiary references may supply details and means for achieving an ECR plasma to the combination of Williams & Subramanian, they are also complementary to each for supplying alternate configurations for achieving the ECR microwave plasma, as well as complementary teachings on parameter control therefore.

6. Either Makker et al (5,942,277) or Narayanan (5,486,357) as previously discussed have teachings concerning RF plasma treatment of tubular substrates, thus remain analogous to those aspects of Williams et al (4,927,676), and cumulatively considered with respect to the above rejection.

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7. Claims 1, 4, 8, 10, 16-17, 19, 21-22, 24-25, 27-28, 31, 33, 36 and 49-52 are rejected under 35 U.S.C. 102(e) as being anticipated by Conover et al (6,136,389), as discussed in section 8 of the action mailed 12/17/04.

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To reiterate, Conover et al teach plasma treatment of porous substrates that may be tubular; may be materials such as glass or plastic (or non porous plastic), which have been exposed to organometallic vapors such as platinum hexafluoroacetylacetonate; where the plasma treatment may use gases, such as inert (Ar), H₂, O₂, fluorocarbons, or have an additive exemplified by propylene; plasma may use frequencies from 50 Hz to 10 GHz, where 13.56 MHz is taught useful, but also it is taught "Also well known in the art are potential beneficial modifying means of increasing the ionization potential and/or providing spatial control of the plasma through the use of separate magnetic fields, i.e., electron cyclotron resonance (ECR) microwave plasma technique" (col. 3, line 3-7; claim 11); where the plasma causes decomposition of an organometallic precursor to deposit metal (Pt or Au) on the exposed surface that may be limited to interior or exterior of tubes. Note that this decomposition on the exposed surface explicitly reads on the option of chemical bond scission. After platinization (metallization) a subsequent coating may be applied, with such suggested coating including plasma polymerized ones or propylene monomers useful in biomedical applications; with suggested applications including Pt/Au coat then attaching biological probes, enzymes, and the like (col. 16, lines 30-31), thus reading on subsequent treatment to coat with a bioactive material. Particularly see, the abstract; col. 2, lines 9-29 and 50-col. 3, line 30 for plasma control; col. 3, lines 31-35 (continuous treatment of tubes) 46-50; col. 4, lines 6-35 and 46- col. 6, line 20, esp. col. 5, line 1-25 (#12 & 13 plasma and single side deposition in tube), 15(a-b) for various subsequent coats, and 17 for biomedical applications. Examples 2, 4, 5, 7, 8-10 (inner tube diameter 7 mm), 15, 16, 17 (A) and 18 directed to tubular substrates, only 16 indicating interior + exterior coating; col. 13, line 64 - col. 14, lines 8 and 63-67 for gases; Col. 15, lines 3-10 for interior surfaces coating, lines 30-40 for applications, lines 51 – col. 16, line 10 for substrate materials and col. 16, lines

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11-33 for further coating sequences. Particularly note claims 1, 3-4 and 11-13, with the claimed magnetic field in the reaction zone finding its support in Conover in the disclosure of the optional use of ECR. While Conover does not give the formula in applicant's claim 8, it must have been satisfied to produce the taught ECR plasma and the magnetic field must have been selected to do so. Note that noble metals, such as Pt or Au, are generally considered to have anti-microbial or anti-inflammatory properties, hence subsequent Complexes made therewith for the bioactive options could be considered inherently inclusive of such properties. Also, plasma treatments due to the energy and radiations involved, inherently affect a sterilization process or effect, regardless of the other intended results.

That Conover et al teach their initial plasma treatment of porous substrates that may be tubular causes decomposition of an organometallic precursor to deposit metal (Pt or Au) on the exposed surface that may be limited to interior or to exterior of tubes reads on applicant's claimed plasma treatment of generic tubular substrates, where the chemical &/or physical modification includes chemical bond scission. Since, after platinization (metallization) a subsequent coating may be applied (examples on col.15, lines 25-40, including bio-applications), this reads on subsequent coating as amended, hence applicant's amendments do not remove the rejection & arguments remain unconvincing.

8. Claims 5-7, 11-15, 22, 25-26, 34-35 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conover et al, as discussed in section 9 of the action mailed 12/17/04.

To reiterate, Conover et al do not provide specific parameters for use when ECR plasmas are employed, however the magnetic field strengths known to be useful to produce ECR conditions are generally in the claimed range, and Conover et al provide discussion on the importance of control of gas flow and pressure to localize the plasma region and provide a useful guide to adjusting power (Watts) and flow rate according to gases employed and reactor size/shape, hence it would have been obvious to one of ordinary skill in the art to employ such teachings with the ECR option to optimize reaction parameters via routine experimentation, where claimed values would have been within expected optimization.

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While the examples where particular internal diameters (ID) as claimed are recited, are not particularly directed to ECR plasma, it would have been obvious to one of ordinary skill in the art to treat such substrates with the option of ECR plasma due to ECR's suggested benefits, and due to the examples suggested desirability of treating substrates of such ID via taught processes.

While the only specifically mentioned attached biological material in Conover is enzymes, bioaffinity operations are taught in general, with specific uses listed as "medical diagnostic...DNA probes,
and biopurification and separation operations...application in synthesis...of peptides" (col. 15, lines 2840), hence when considered with Pt or Au's inherent properties, would have suggested the obviousness of
uses, where the materials deposited are anti-microbial or anti-inflammatory or effect all growth as
claimed, because these teaching suggest the coatings would have properties of these types.

9. Claims 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conover et al as applied to claims 1, 4-8, 10-17, 19, 21-22, 24-28, 31, 33-37, 39 and 49-52 above, and further in view of Wilhelm & Kanai et al (5,976,257), & optionally Kieser et al for claim 53, as discussed in section 12 of the action mailed 12/17/04 & section 7 of the action mailed 9/7/2005.

Independent claims 53 & 54 have not been amended, so it remains relevant as previously stated Conover et al teaches use of use of "techniques known in the art for 'single side' or 'counter flow' low pressure chemical vapor deposition (LPCVD)... can be modified to obtain controlled platinization layer or zone within the interior wall of the substrate tubing, for deposition at a specific location on or along the wall", where the terminology suggests that flow hence pressure is involved. Applicant asserted with out support that this only refers to different chemical deposition (p.15 of 6/20/05 response), however 'single side' or 'counter flow' LPCVD while inclusive of providing chemical differentiation interiorly or exteriorly, is clearly suggestive of different pressures, as such means are typical ways of producing taught flow effects.

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To reiterate, in teaching platinizing (i.e. plasma treating) interior or exterior, selectively (col. 5, lines 10-30, esp. 15-25), Conover et al does not give specific details, but mention use of "techniques known in the art for 'single side' or 'counter flow' low pressure chemical vapor deposition (LPCVD)... can be modified to obtain controlled platinization layer or zone within the interior wall of the substrate tubing, for deposition at a specific location on or along the wall". While this does not specifically disclose the use of a pressure differential between interior and exterior of the tube, the terminology suggests that flow, hence pressure is involved. Also while directed specifically to porous substrates, the listing of substrates to which Conover et al's process may be applied, also includes non-porous plastic (col. 15, line 65).

ECR plasma are known to be limited by pressure, and use of pressure differentials between areas to be coated and those not to be coated are known in the art, with Wilhelm (discussed previously; abstract; figure; summary) showing use of higher external pressure and lower internal pressure to localize ECR plasma treatment inside a tubular substrate thus treating its interior surface. The Kanai et al reference (Abstract; figures, cover exemplary; col. 21, lines 54 – col. 22, line 55, esp. lines 4-10 and 35-53) use the substrate to create an isolated tubular area that employs a pressure differential to create plasma inside the tube, such that plasma treatment occurs inside, but not outside and that the shape withstands the pressure difference between inside and outside the plasma chamber/ zone. Given these teaching concerning relevant microwave plasmas and use of pressure in localizing, where the plasma occurs with respect to a tube shaped substrate to be coated, and consideration of the above discussions/teachings of Conover et al concerning one side coating in low pressure CVD process, it would have been obvious to one of ordinary skill in the art to control the pressure in the tubes of Conover et al, such that only the desired surface, whether interior or exterior (or both) had the correct pressure to sustain the ECR plasma, so that only areas to be coated/treated were exposed to plasma. Note that this would be easiest with the taught non-porous plastic substrates, but even with porous ones one ordinary skill would have found it

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obvious to adjust flow and evacuation rates to maintain effective pressure differences, especially considering the teaching of Kanai where mesh or "punching" boards are used in maintaining pressure differences. Kieser et al is optionally considered for continuous elongated substrate configurations where exteriors are coated, which would have been consistent with Conover et al's own continuous substrate teachings, where the principles expressed in Wilhelm or Kanai et al for localizing plasmas to an interior would apply equally to an exterior where the inside is not to be coated, as it is still the same pressure ranges that make plasma possible or not.

Note as ECR plasmas are shown by the art to be localized & dependent on a combination of both pressure and localized magnetic field, that the exclusion of one parameter meeting the required conditions would clearly be recognized by a competent practitioner to exclude the presence of the ECR plasma in the region lacking the required conditions, thus for hollow tubular substrates which are airtight between there in interior and exterior, it would have been abundantly clear to one of ordinary scale the supply of the correct pressure to only the side of the tube that was desired to be plasma treated, would clearly have limited the plasma treatment to that locale, especially given teachings of Wilhelm (285) or Kanai et al (5,976,257), or Kieser et al, which suggests such, and the more general teachings of Conover et al. which appear to expect one of ordinary skill in the art to be capable of providing means for differential plasma treatments of interior and exterior, such as via differential pressure.

- 10. Claims 53-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Subramanian (5,914,115) in view of Williams et al. (4,927,676), further considering Conover et al as applied to claims 1, 4-8, 10-19, 21-28, 31, 33-39 and 49-52 above, and further in view of Wilhelm (285) & Kanai et al (5,976,257), & optionally Kieser et al for claim 53, for reasons as discussed above in sections 9 & 5.
- 11. Applicant's arguments filed on 3/9/2006 & 4/24/2006 and discussed above, have been fully considered but they are not persuasive.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

6/20&21/2006

MARIANNE PADGETT PRIMARY EXAMINER